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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/530,351  
Filing Date: April 06, 2005  
Appellant(s): BOUCHERIE, BART GERARD

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Patrick Buechner  
For Appellant

**EXAMINER'S ANSWER**

**\*\*Note:** The communications mailed 13 July 2009 and 20 July 2009 are hereby vacated. **\*\***

This is in response to the appeal brief filed 14 July 2008 appealing from the Office action mailed 15 February 2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct.

Appellant does not address or argue any of the rejections of the dependent claims made under 35 USC 103.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

WO 01/70311 (Chiba), using translation of the related document JP 2001-259031

5782803	Jentzen	07-1998
5030406	Sorensen	07-1991
4861335	Reynolds	08-1989
3659749	Schwartz	05-1972

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiba (WO 01/70311), using a translation of the related document JP 2001-259031. Regarding Claim 1, Chiba shows that it is known to carry out a method of manufacturing plungers for medical syringes (para. 0001), said plunger comprising at least two parts including a longitudinal plunger body (Figure 1, element 5) made of plastic and a piston body provided at the front end of the plunger body (Figure 1, element 6), which piston body comprises a plastic which is softer than the plastic of the plunger body (para. 0011-0013), wherein said plunger or at least part of the plunger is formed by first manufacturing the piston and then the plunger body by means of injection molding, and wherein the plunger body is injected against the piston body, the piston having a front side and a side wall and being formed free of any flash lines (Figure 1; para. 0016-0018).

Regarding Claim 3, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the piston body and the plunger body are connected solely by adhesion between the plastics out of which they are made, without any meshing parts (Figure 1, para 0018).

Regarding Claim 4, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein at least one inwardly directed part is formed on the piston body and use is made during injection molding of a mold part having a protruding part in which one or several lateral recesses are provided, such that the mold part may be removed from the piston body due to the elastic flexibility of the piston body (Figure 5; para. 0002-0004; it is interpreted that the mold part will be the

Art Unit: 1791

negative image of the molded body- when the piston has a inwardly directed part, the mold part will have a protrusion to form the inwardly directed part).

Regarding Claim 5, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the plastic forming the piston body is provided in a respective mold cavity via the back side of the piston body to be formed (Figure 2(c)).

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Jentzen (U.S. Patent 5,782,803). Jentzen shows that it is known to carry out a method for manufacturing plungers for medical syringes having at least a piston body comprising forming a part of the piston body at the location of the piston body which protrudes frontally from a front side of the piston body and which, when the plunger is located in a syringe, can penetrate at least partially through an outlet of the syringe (Figures 4-6; Column 3, lines 41-50), wherein the piston body part is formed of a material which is different from the material of the piston body, and herein the materials for forming the piston body and the protruding portion are formed with known processes (e.g. injection) such that the piston body can be made in one piece with a plunger body belonging to the plunger (Figure 7, element 300, 202).

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba, in view of Sorensen (U.S. Patent 5,030,406).

Regarding Claim 6, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show multicavity molding. Soresnsen shows that it is known to carry out a multicavity molding process wherein one article is formed in a first mold after which the article, while it is still held in a first part, is presented to a second mold cavity in which a second element of the article is then injected against the first article by means of injection molding, and wherein the mold cavities are of the desired final article shape, and the two plastics are connected to each other due to adhesion between the plastics (Figures 1-8). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use

Sorensen's multistep/multicavity molding process during Chiba's molding method in order to most efficiently form two parts of an article at the same time.

Regarding Claim 7, Chiba shows the process as claimed as discussed in the rejection of Claim 6 above, but he does not show simultaneously forming a second portion of the article at the same time as a first portion. Sorensen shows that it is known to carry out a method wherein the second body is formed such that it connects to first body, a subsequent first body is simultaneously being formed by means of a connector nozzle with which the first body is formed but in another mold cavity (Figures 1-8). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Sorensen's multistep/multicavity molding process during Chiba's molding method in order to most efficiently form two parts of an article at the same time.

Claim 8 is rejected under 35 USC 103(a) as being unpatentable over Chiba. Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the plunger body is formed in a mold, after which a mold part with the plunger body in it is presented against other mold parts in which the piston body is formed (Figures 2(a)-2(c); para. 0015). Although Chiba's process molds the plunger first and then the piston, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to mold the piston first followed by the plunger because selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. (*In re Burhaus*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946)).

Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba, in view of Schwartz (U.S. Patent 3,659,749).

Regarding Claim 9, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show an accessory at a front side of the piston body. Schwartz shows that it is known to carry out a method of manufacturing a piston and plunger including forming a plunger and an accessory located at a front side of the piston body, wherein the accessory is made of a different material than the piston

Art Unit: 1791

(Figure 3, element 42). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's method in order to provide an intermixing syringe (see Schwartz, Column 2, lines 14-18).

Regarding Claim 10, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows using an accessory, wherein its material comprises glass (Column 3, lines 61-63; it is being interpreted that glass can be considered a plastic material of sorts since it can be melted and reshaped and molded again). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's harder material for the accessory during Chiba's method in order to provide an intermixing syringe (see Schwartz, Column 2, lines 14-18).

Regarding Claim 11, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows that it is known to carry out a plunger/piston manufacturing method including an accessory which comprises a part which extends frontally of a front side of the piston and which, when the plunger is situated in the syringe, can at least partially penetrate an outlet of the syringe (Figure 8, element 112, 117; Column 6, lines 3-44; it is noted that the remaining limitation of the claim is being considered solely as intended use). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's molding method in order to provide a one-way valve in the plunger/piston assembly (See Schwartz, Column 6, lines 3-5).

Regarding Claim 12, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows that it is known to make a plunger/piston assembly including an accessory comprising a part which enables creation of a passage between the front side and a rear side of the piston body when emptying the syringe (Column 6, lines 3-44; it is noted that the remaining limitation of the claim is being considered solely as intended use). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention

Art Unit: 1791

was made to use Schwartz's accessory during Chiba's molding method in order to provide a one-way valve in the plunger/piston assembly (See Schwartz, Column 6, lines 3-5).

Regarding Claim 13, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows that it is known to carry out a method of making a plunger/piston assembly including an accessory made as a separate part provided on a front side of the piston body (Figure 14). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's molding method in order to provide a one-way valve in the plunger/piston assembly (See Schwartz, Column 6, lines 3-5).

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba, in view of Reynolds (U.S. Patent 4,861,335).

Regarding Claim 14, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show connecting the piston to the plunger at a later stage. Reynolds shows that it is known to carry out a method of forming a piston and a plunger, wherein the piston is attached to the plunger at a later stage after molding of the plunger and part of the piston (Column 4, lines 56-68). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Reynolds' attachment process during Chiba's molding method in order to enable the attachment of various pistons to the end of the same plunger.

Regarding Claim 15, Reynolds shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show connecting the plunger to a drive element. Reynolds shows that it is known to carry out a method wherein the plunger cooperates with an associated drive element (Column 5, lines 57-68; Column 6, lines 1-3, 20-54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Reynolds' drive element in combination with Chiba's plunger in order to accurately move and position the plunger during consumer use.



**(10) Response to Argument**

**(Claim 1- Heading (C))**

Applicant contends that Chiba does not show the claimed invention because he does not show molding a plunger body against a piston body. This is not persuasive because, even as applicant points out, paragraph [0019] discloses that the gasket 6 (i.e. the claimed piston) is provided in the mold before the material is injected that forms the plunger 5. Therefore, since the gasket 6 is in the mold before the material is injected that forms the plunger 5, the plunger 5 will be molded against the gasket 6 (i.e. piston body). It is maintained that Chiba shows this aspect of the claimed invention.

Applicant also contends that Chiba does not show the claimed invention because he does not show forming a piston free of any flash lines and/or gate points for the plastic. This is not persuasive because Figure 1 of Chiba clearly shows a gasket 6 (i.e. piston body) that is free from any flash lines and/or gate points for the plastic. Although Figures 2(a)-2(c) show a gasket 6 (i.e. piston body) having a gate point, this gate point is removed to the extent that the resulting gasket, shown in Figure 1, is free from any flash lines or gate points. Note that the claim does not require the piston to be free of any flash lines and/or gate points as it exits the die, for example, but the claim only requires the piston being free from flash lines and/or gate points. It is therefore interpreted that as long as the final form of the molded gasket 6 (i.e. piston body) is free from flash lines and/or gate points, Chiba's gasket 6, as shown in Figure 1, meets the claimed limitation. The claim does not preclude a finishing step that would remove any flash lines or gate points resulting from the molding process.

**(Claim 16- Heading (D))**

Applicant contends that Jentzen does not show the claimed invention because he does not show a protruding piston body being formed from a different material than the piston body. Applicant contends that Figures 4-6 do not show the claimed configuration. This is not persuasive because the examiner did not rely on Figures 4-6, an alternate embodiment, to show the claimed limitation. In the rejection, the examiner

Art Unit: 1791

clearly refers to Figure 7, also an alternate embodiment of Jentzen's invention. In Figure 7, the two different materials of the piston 300 and the protruding piston body 202 are noted by the different cross-hatching of the two elements. Also see Column 3, lines 42-51 for a general discussion on different materials used for the piston 300 versus the plunger 200. Figure 7 is described at Column 5, lines 6-21. A discussion of the element 202, considered to be the protruding piston body, occurs at Column 5, lines 11-12, 17-18, or 20. Although Jentzen sometimes refers to 202 as the plunger end, it is being interpreted that since it protrudes from the piston body, it can and is reasonably be considered a protruding piston body that is made from a different material as the piston.

Applicant also contends that Jentzen does not show the claimed invention because he does not show forming the piston body and protruding part by injecting the materials against each other such that the piston body is made in one piece with a plunger body of a plunger. Applicant seems to argue that since there is an alleged deficiency with Jentzen not showing two materials, as previously discussed, Jentzen cannot show the injection of each material, instead of pointing out where Jentzen does not show injection molding of each part.

As noted in the previous paragraph, it is maintained that Jentzen does show a piston and protruding piston body made of two different materials. Applicant admits on page 16 of the Brief that in Figure 7, the element 300 is a separate element from element 202. Jentzen teaches injection molding of his plunger element 200 (Column 3, lines 46-50) and the piston element 300 is made (e.g. molded) of an elastomeric material (Column 3, lines 44-45). At Figure 7 and Column 5, lines 15-16, Jentzen notes that the piston 300 is in a recess, not easily available or accessed, and surrounded by element 200. Using these teachings, it follows that the material for the plunger can reasonably be injection molded against and around the piston material, to meet the claimed "injected against one another", in order for the piston and plunger bodies to be made in one piece, i.e. contained within one piece.

Art Unit: 1791

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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